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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stewart Cole

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EXAMINER

BABIC, CHRISTOPHER M

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1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/505,405	Applicant(s) COLE ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,8,10-13 and 15-70 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 and 23-59 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5 and 7 is/are allowed.
- 6) ☒ Claim(s) 8,10-13,19-22 and 60-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim(s) 1, 5, 7, 8, 10-13, and 15-70 are pending. Claim(s) 1, 5, 7, 8, 10-13, 19-22, and 60-70 are under examination. The following Office Action is in response to Applicant's communication dated September 20, 2010.

Claim Rejections - 35 USC § 112 - Indefiniteness - New Grounds

The following rejection is made in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 10-13, 19-22, 60, and 64-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The metes and bounds of claims 8, 10, 19-23, 60, and 64-70 are indefinite because claim 8 recites a fragment "consisting of" in line 2, which is read as closed language, as well as reciting "wherein the fragment is" in line 3, which absent a specific definition in the specification the word "is" is read as equivalent to "comprising" or open language (see MPEP 2111.03). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is

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considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).

(b) The metes and bounds of claims 11-13, 19-23, 60, 69, and 70 are indefinite because as read by the examiner the claimed nucleic acid fragment must contain at least 2 of the recited primer sequences, which totals greater than "at least 12..." consecutive nucleotides of SEQ ID NO: 4.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant's claim amendments and supplemental remarks are sufficient to overcome the rejection of claim(s) 5 over Brennan, and the rejection of claims 8, 19, 69, and 70 over NCBI. Thus, the rejections have been withdrawn.

Claim Rejections - 35 USC § 103 - Withdrawn

Applicant's claim amendments and supplemental remarks are sufficient to overcome the rejection of claim(s) 5 and 11-13 over Fodor, and the rejection of claims 5 and 11-13 over Santos and NCBI. Thus, the rejections have been withdrawn.

Claim Rejections - 35 USC § 103 - New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim(s) 8, 10, and 61-64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. 2001/0053519 A1).

As an initial matter, as recited above, the claimed invention does not require that the nucleic acid fragment necessarily include the sequence of both recited primers. Furthermore, the claimed invention does not require a specific type of amplification method nor template sequence. Furthermore, even assuming the fragment is recited to require that both recited primers be part of the claimed nucleic acid fragment, such fragment remains recited in a manner that encompass any nucleic acid fragment such as a 20-mer sequence for example.

Fodor teaches an "n-mer" array comprising every permutation of a 10-mer oligonucleotide (example 2, for example). The reference further suggests the

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production of solid supports comprising a set of every permutation (4^n) of different length oligonucleotides or n-mers in a range from 2-25-mers ([0100]-[0104]). For example, a 20-mer "n-mer array" product would have comprised every possible oligonucleotide of 20 bases in length. Thus, a product comprising a purified or isolated oligonucleotide of 20 contiguous nucleotides of SEQ ID NO: 4 (claim 8), or SEQ ID NOs 13-18 (claims 10 and 61-64) would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The grounds of the rejection are not based on an inherent feature that was not known at the time of invention or later established. The formula to provide for each sequence is clearly taught within Fodor. Thus, the exact structure of every 20-mer oligonucleotide sequence on an array is suggested. In other words, it was not conjecture within the prior art that a 20-mer n-mer array would have comprised SEQ ID NO: 13. The exact structure of SEQ ID NO: 13 would have been present within the 20-mer n-mer array suggested by Fodor.

Thus, the rejection is maintained.

2. Claim(s) 8, 64, 69, and 70 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Santos et al. (J Med Microbiol. 1993 Oct;39(4):298-304) in view of NCBI (GENBANK Accession No. U15183; 9 March 1995).

As an initial matter, as recited above, the claimed invention does not require that the nucleic acid fragment necessarily include the sequence of both recited primers. Furthermore, the claimed invention does not require a specific type of amplification method nor template sequence. Furthermore, even assuming the fragment is recited to require that both recited primers be part of the claimed nucleic acid fragment, such fragment remains recited in a manner that encompass any nucleic acid fragment such as a 22-mer sequence for example.

Santos teaches designing a probe sequence to the *Mycobacterium leprae* genome (pg. 299, Southern hybridization, probe ML-97 5'- TTTTAGTGTG CATGTCATGG-3', for example). Santos does not specifically teach a sequence recited in claims 5, 8, or 11.

However, it is first noted that the *M. leprae* genome sequence, the sequence from which the Santos oligonucleotide was derived, is a sequence that was well known at the time of invention (see GENBANK Accession Nos. U15183). Thus, the binding site of a claimed oligonucleotide, a 22-mer for example, is suggested within the sequence disclosed by U15183 (see NCBI figure above).

Applicant is directed to *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the

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claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Furthermore, the recent court decision *KSR International Co. v. Teleflex Inc.*, 82 127 SCt 1727 (2007), the U.S. Supreme Court determined that if the combination of the claimed elements was "obvious to try" by a person of ordinary skill, this might show that such a combination was obvious under 35 USC §103. Regarding "obvious to try", the Court stated:

"A person of ordinary skill is also a person of ordinary creativity, not an automaton. The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

Thus, since the claimed sequences simply represent structural homologs of those sequences disclosed in the prior art, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds, the claimed 22-mer sequence within NCBI U15183 is *prima facie* obvious over the cited references in the absence of secondary considerations.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Neither Santos nor NCBI must be related entirely to SEQ ID NO: 1 or SEQ ID NO: 4, i.e. disclose the full-length sequences, to establish obviousness. The fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Thus, the fact that Applicant has discovered that the claimed sequences can be used as probe or primer specific for SEQ ID NOs: 1 and 4 cannot be the basis for patentability, absent a secondary consideration, when the claimed sequences simply represent structural homologs of those sequences disclosed in the prior art.

Thus, the rejection is maintained.

3. Claim(s) 21 and 60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over NCBI (GENBANK Accession No. U15183; 9 March 1995) in view of Laqueyrie et al. (U.S. 6,221,353 B1).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach recombinant cells.

Laqueyrie teaches the production of recombinant cells comprising cosmid(s) for the study of such cosmid(s) (col. 17, lines 50-65, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to incorporate the NCBI

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cosmid into an E. coli cell for example since Laqueyrierie suggests such a product to produce copies of target cosmid sequences for further study.

Response to Arguments

Applicant's arguments have been addressed in the response(s) set forth above.

Allowable Subject Matter

Claims 1, 5, and 7 are allowed.

Claims 11-13, 20, 22, and 65-68 are free of the prior art but rejected for other reasons.

Conclusion

Claims 1, 5, and 7 are allowed.

Claims 8, 10-13, 19-22, and 60-70 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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